



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 285067 COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule

ARTG entry for Medicine Registered
Sponsor Amdipharm Mercury Australia Pty Ltd
Postal Address PO Box 333, NORTH SYDNEY, NSW, 2059
 Australia
ARTG Start Date 24/04/2017
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective date | 20/10/2017 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Prophylaxis and treatment of pernicious (Addisonian) anaemia and other macrocytic anaemias associated with vitamin B12 deficiency. Treatment of optic neuropathies such as tobacco amblyopia and Leber's optic atrophy.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

| Type | Material | Life Time | Temperature | Closure | Conditions |
|---------|--------------------|-----------|--------------------------------|--------------|--------------------|
| Ampoule | Glass Type I Clear | 24 Months | Store below 25 degrees Celsius | Not recorded | Protect from Light |

Pack Size/Poison information

| | |
|------------------|--|
| Pack Size | Poison Schedule |
| 3 x 1mL ampoules | Not scheduled. Not considered by committee |

Components

1. COBAL-B12 INJECTION hydroxocobalamin acetate solution for injection ampoule

| | |
|--------------------------------|-----------------------|
| Dosage Form | Injection, solution |
| Route of Administration | Intramuscular |
| Visual Identification | clear pale red liquid |

Active Ingredients

| | |
|---------------------------------|-----------------|
| Hydroxocobalamin acetate | 1.044 mg |
|---------------------------------|-----------------|

Public Summary

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